IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA, ex. rel. [UNDER SEAL],	)	
Plaintiff,	)	**No. _____**
v.	)	**JURY DEMAND**
[UNDER SEAL],	)	
Defendant.	)	

FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA, ex. rel. PAUL DORSA,	)	
Plaintiff,	)	**No. _____**
v.	)	**JURY DEMAND**
MIRACA LIFE SCIENCES, INC.	)	
Defendant.	)	

SEALED QUI TAM COMPLAINT

Relator, Paul Dorsa, brings this action on behalf of himself and in the name of the United States of America, by and through his undersigned attorneys, and alleges as follows:

I. INTRODUCTION

1. Relator, Paul Dorsa ("Relator" or "Mr. Dorsa"), a resident of Williamson County, Tennessee, on behalf of himself and the United States of America ("United States") brings this action to recover treble damages, civil penalties, and costs under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and to recover damages and other monetary relief under the common law and equitable theories of unjust enrichment and payment by mistake of fact.

2. This action arises from Defendant Miraca Life Sciences, Inc.'s ("Defendant" or "Miraca") conspiracy to defraud Medicare by using illegal practices under the Stark and Anti-Kickback laws to induce pathology referrals from physicians. Defendant has, for years, offered Medicare providers thousands of dollars worth of incentives with the expectation, and, in some instances, explicit agreement, that these providers will send Defendant pathology referrals. The

action further encompasses the false claims Defendant knowingly presented to, or caused to be presented to, the United States, in violation of the United States False Claims Act ("FCA") and common law, and the conspiracy underlying these claims.

3. Defendant is an anatomic pathology laboratory services company servicing Medicare providers located in nearly every state in the United States. It offers pathology services in the fields of dermatology, gastroenterology, hematology, and urology. It has labs in Newton, Massachusetts; Glenn Burnie, Maryland; Irving, Texas; Phoenix, Arizona; Tucson, Arizona; Cleveland, Ohio; and Honolulu, Hawaii, and has approximately 830 employees, including roughly 70 pathologists. Defendant has annual revenues approaching approximately $250 million.

4. Defendant submits millions of dollars worth of claims to Medicare every year, certifying therewith that it is complying with applicable Mediare statutes, regulations, and rules.

5. The claims submitted to Medicare are for pathology services performed on cases referred to Defendant from thousands of doctors across the United States.

6. In many cases, referrals from these doctors to Defendant are tainted by arrangements that violate federal law, specifically the Stark and Anti-Kickback laws, and therefore render these claims false within the meaning of the False Claims Act.

7. Specifically, Defendant has knowingly and willfully paid and offered to pay remuneration to doctors to induce or reward referrals, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and has knowingly and willfully submitted claims based on a prohibited financial relationship, in violation of the Stark Law, 42 U.S.C. § 1395nn.

8. Defendant has also conspired with its employees, as well as the physicians to whom it has offered or paid remuneration and/or with whom it has a prohibited financial

relationship, to submit tainted Medicare claims to Medicare by virtue of its knowing, intentional, and willful violations of the Stark and Anti-Kickback laws.

II. JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1367 and 31 U.S.C. §§ 3730 and 3732.

10. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because Defendant transacted and/or continues to transact business in the Middle District of Tennessee.

11. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant transacted and/or continues to transact business in the Middle District of Tennessee.

III. PARTIES

12. Plaintiff in this action is Relator Paul Dorsa on behalf of himself and the United States.

13. Relator Paul Dorsa brings this action pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b)(1).

14. Relator has served a copy of this Complaint, together with a written disclosure statement setting forth and enclosing all material evidence and information he possesses, upon the United States, consistent with 31 U.S.C. § 3730(b) and Fed. R. Civ. P. 4(i).

15. Relator has complied with all other conditions precedent to bringing this action.

16. Though Relator is aware of no public disclosures of the information contained in his Complaint, should such a disclosure exist, Relator is the original source of, and has direct and independent knowledge of, all publicly disclosed information on which any allegation herein might be deemed based, and has voluntarily provided such information to the United States.

17. Relator is employed by Defendant as Senior Vice President of Commercial Operations. Through his employment with Defendant, Relator has personal knowledge of the false claims that Defendant presented or caused to be presented to the United States, as well as the conspiracy underlying those claims.

18. Defendant Miraca Life Sciences, Inc. is a Delaware corporation with its headquarters in Irving, Texas. It is a wholly-owned subsidiary of Miraca Holdings, Inc., a Japanese corporation.

IV. FEDERAL STATUTORY BACKGROUND

A. The United States False Claims Act

19. The United States False Claims Act ("FCA"), at 31 U.S.C. § 3729 contains several sections giving rise to liability. Section 3729(a)(1)(A) creates liability for anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the Government ("Presentment False Claims") and section 3729(a)(1)(C) creates liability for anyone who "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)" ("Conspiracy False Claims").

20. The Fraud Enforcement and Recovery Act of 2009 ("FERA") amended the FCA, substantially increasing the range of behavior giving rise to False Claims Act cases, and lightening the burden on the Government.

21. Before FERA's amendments, the FCA provided, at 31 U.S.C. § 3729(a)(1) (now (a)(1)(A)), that liability attaches when a defendant "knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval." FERA

amended this section by removing the phrase "to an officer or employee of the United States Government or a member of the Armed Forces of the United States."

22. Before FERA's amendments, the FCA provided, at 31 U.S.C. § 3729(a)(3) (now (a)(1)(C)), that liability attaches when a defendant "conspires to defraud the Government by getting a false or fraudulent claim allowed or paid." FERA amended this section by removing this phrase and substituting "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)."

23. The FCA defines the term "claim" to mean

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that -- (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government -- (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded . . . .

31 U.S.C. § 3729(b)(2)(A).

24. The FCA defines the terms "knowing" and "knowingly" to mean that a person, with respect to information: (1) "has actual knowledge of the information"; (2) "acts in deliberate ignorance of the truth or falsity of the information"; or (3) "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). The FCA further provides that "no proof of specific intent to defraud" is required. 31 U.S.C. § 3729(b)(1)(B).

B. <u>The Stark Law and the Anti-Kickback Statute</u>

25. The Stark Law ("Stark"), 42 U.S.C. § 1395nn, prohibits physicians from referring Medicare patients for designated health services (including, in the context of this Complaint,

laboratory pathology services) to an entity with which the physician has a prohibited "financial relationship."

26. Stark also prohibits providers such as hospitals, laboratories, and others (known as "designated health services entities") from submitting claims to Medicare for services resulting from a prohibited referral (i.e., a referral made by a physician to a designated health services entity with whom the physician has a prohibited financial relationship).

27. Prohibited financial relationships can occur in a number of ways, including through impermissible ownership interests (e.g., where a physician owns fully or partially the entity to which (s)he is making the referral, or where a physician's family close family member fully or partially owns the entity to which (s)he is making the referral) and impermissible compensation arrangements (e.g., providing free gifts, providing services at below-market-value rates, or selling or leasing real estate at below-market-value rates).

28. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), prohibits the offering, paying, soliciting, or receiving anything of value intended to induce or reward referrals or to generate Medicare health care business. The "anything of value" includes "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind," *id.*, e.g., monetary payments, free or below-market value services, goods, real estate, and other transactions.

C. The Intersection of the False Claims Act and Stark/Anti-Kickback

29. Under the section 6402 of the Patient Protection and Affordable Care Act of 2010, violations of the Anti-Kickback Statute and Stark Law can form the basis of False Claims Act violations because any claims submitted to Medicare are tainted, and therefore false within the meaning of the False Claims Act. ("(f) HEALTH CARE FRAUD.— (1) KICKBACKS.—

Section 1128B of the Social Security Act (42 U.S.C. 1320a–7b) is amended by adding at the end the following new subsection: '(g) In addition to the penalties provided for in this section or section 1128A, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code.'").

30. Even before the passage of the Patient Protection and Affordable Care Act of 2010, violations of the Anti-Kickback Statute and the Stark Law could form the basis of a False Claims Act case. *See U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 54 (D. Mass. 2011) ("Moreover, courts, without exception, agree that compliance with the Anti–Kickback Statute is a precondition of Medicare payment, such that liability under the False Claims Act can be predicated on a violation of the Anti–Kickback Statute.") (collecting cases); *see also U.S. ex rel. Pogue v. Am. Healthcorp, Inc.*, 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996); *U.S. ex rel. Dennis v. Health Mgmt. Associates, Inc.*, 3:09-CV-00484, 2013 WL 146048 (M.D. Tenn. Jan. 14, 2013) ("[I]t is well established that claims for remuneration made to the government in violation of AKS and Stark may violate the FCA.").

V. FACTS

A. The Electronic Medical Records Safe Harbor Donation Program

31. In August of 2006, the United States Department of Health and Human Services promulgated final rules allowing certain non-physician healthcare providers to pay some of the cost (up to 85% of software and services) of transitioning physicians over to electronic medical records ("EMR")[1] systems (the "EMR Safe Harbor Program").

[1] Health and Human Services, and other government agencies, often use the equivalent terms "electronic health records" or "EHR."

32. The goal of this program was to help move all physicians over to electronic medical records by 2014; Congress also passed an appropriation for grants aimed at the same purpose.

33. The specific forms these rules took were an exception to the Stark Law and a companion safe harbor provision to the Anti-Kickback statute. The Stark exception is found at 42 C.F.R. § 411.357(w) and the Anti-Kickback safe harbor is found at 42 C.F.R. § 1001.952(y). The Stark exception and the Anti-Kickback safe harbor (the "Safe Harbors") are virtually identical.

34. By following the provisions of the Safe Harbors, providers could make donations to physicians for up to 85% of the cost of electronic medical records systems (excluding hardware) without violating federal law.

35. The Anti-Kickback provision requires that, in order to qualify for the safe harbor, "[n]either the beneficiary nor the recipient's practice (or any affiliated individual or entity) [can make] the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor." 42 C.F.R. § 1001.952(y)(4).

36. The Stark provision requires that, in order to qualify for the exception, "[n]either the physician nor the physician's practice (including employees and staff members) [can make] the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor." 42 C.F.R. § 411.357(w)(5).

37. The Anti-Kickback provision also requires that, in order to qualify for the safe harbor, "[n]either the eligibility of a beneficiary for the items or services, nor the amount or nature of the items or services, [can be] determined in a manner that directly takes into account

the volume or value of referrals or other business generated between the parties." 42 C.F.R. § 1001.952(y)(5).

38. The Stark provision also requires that, in order to qualify for the exception, "[n]either the eligibility of a physician for the items or services, nor the amount or nature of the items or services, [can be] determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties." 42 C.F.R. § 411.357(w)(6).

B. The Meaningful Use of Electronic Medical Records Program

39. In 2010, the Department of Health and Human Services created a "meaningful use" ("MU") program, under which physicians and others who can demonstrate that they are making "meaningful use" of an electronic medical records system to improve patient care are eligible for bonuses. This program was another effort by HHS to increase the use of electronic medical records systems in the healthcare industry. For their participation, physicians can receive up to $44,000 over the life of the program.

C. The EMR Donations Fraud Scheme

40. Miraca's business depends on pathology lab work referrals from physicians in the dermatology, gastroenterology, hematology, and urology fields.

41. After the EMR Safe Harbor Program was implemented in 2006, Miraca saw a way to use the program to induce referrals of pathology services from physicians. Under the EMR Safe Harbor Program, Miraca, and companies like it, are strictly prohibited from giving EMR donations to physicians in return for, or in consideration of, referrals.

42. Despite this prohibition, over the course of several years, Miraca has been exchanging EMR donations for referrals in violation of the Stark and Anti-Kickback laws,

calibrating the amount of the EMR donations it makes to its forecasted return on investment ("ROI").

43. Miraca's computes its ROI based on the numbers of referrals that will be (and are) sent to Miraca in return for the EMR donation, and the aggregate value of these referrals.

44. Miraca has actively recruited physicians with the promise of thousands, or sometimes tens of thousands, of dollars of EMR donations with the understanding that physicians would reciprocate with referrals.

45. The fraudulent process is initiated when a Miraca sales director contacts a physician or physician practice. Either the sales director, or sometimes the physician or physician practice, suggests that Miraca make an EMR donation.

46. Both parties (the Miraca sales director and the physician or physician practice) understand, and in some instances articulate, that an EMR donation from Miraca is contingent on the physician or practice referring pathology cases to Miraca.

47. The Miraca sales director also gets as much information about the physician or practice as possible, with respect to type and volume of referrals that will be made, other companies (if any) offering to make an EMR donation, and the typical number of common procedural terminology (CPT) codes that go along with each referral.

48. An email sent in December of 2012 from Miraca's Regional VP of Sales for the Mid-Atlantic region, Louis Cosentino, is a good example of Miraca's knowing, willful, and illegal practices and procedures with respect to EMR donations. Mr. Cosentino sent an email to the entire Miraca Mid-Atlantic sales team with the subject line "Safe Harbor Donation Criteria." (Email from Louis Cosentino to Jill Baird et al., Dec. 19, 2012, attached as **Exhibit 1**.)

49. In this email, Mr. Cosentino outlined a "list of criteria/questions" that his sales team should be "ready to comment on during the review meeting" to discuss EMR donations:

> To that end, I have prepared the following list of criteria/questions that you should be ready to comment on during the review meeting:
>
> - New or Existing Account – Is this a new or existing account?
> - If new, what is their current lab?
> - If existing, what is the current Miraca *cpm*; and do we have all their volume?
> - Projected Case Volume – Estimate of steady state global volume; and what gives you the confidence that the number is accurate?
> - Are there any TC or PC Cases?
> - Evaluation Period – was there an evaluation/trial period; if so, what was the duration and what was the volume?
> - Practioners – number of physicians, PA's, and MA's; and expectation as to how long they will be working?
> - Offices – how many offices in the practice?
> - Rooms – how many rooms in the practice?
> - Payor Mix – what is the insurance mix and is it favorable to profitability (consult Managed Care group)?
> - Software – what EMR system is the account pursuing; is it a preferred Miraca vendor?
> - Meaningful Use – is this a compelling factor in the client's desire to partner with Miraca?
> - Current Lab – which competitive lab is currently servicing the account?
> - Split account – to what extend do you believe we can acquire 100% of their case volume?
> - Growth – does the practice intend to expand?
> - Influence – is this a strategic account for the territory?
> - Donation – how much is the invoice; does it include training, support, and maintenance?
> - Did anyone try to negotiate a lower price?
> - Recommendation – what percent of the invoice are you recommending?
> - Track Record – what is your track record regarding returns on previous donations?
>
> To the extent we have profit information, we can provide a more informed analysis.
>
> Our current threshold for a donation is approx. 100 global cpm.
>
> Thank you for your diligence in preparing for a successful SH donation review.

(*Id.*)

50. A number of practices and considerations with respect to EMR donations that violate the Stark and Anti-Kickback laws are highlighted in Mr. Cosentino's email. These practices and considerations include (1) the consideration of whether Miraca already has all of the lab work referrals from a customer (i.e., whether there is potential for an increase in referrals), (2) what the projected case volume is, (3) whether Miraca's meaningful use program has induced referrals ("desire to partner with Miraca"), (4) what the sales director's "track record

regarding returns on previous donations" is, (5) what the "profit information" on the healthcare practice is, and (6) the mention of a "threshold for a donation" of 100 cases per month for EMR donations. (*Id.*)

51. A January 2013 email from Kevin Roupp, a Miraca sales director, also serves to illustrate Miraca's knowing, wilfull, and illegal practices with respect to EMR donations. Mr. Roupp was informed that an EMR donation had been approved for a provider called "About Skin," but was upset because he wanted a larger EMR donation authorized. In making his case, Mr. Roupp specified that "Dr. Stoler and Dr. Ho have fully committed to stop using D-Path [another pathology company similar to Miraca] which will add 200 CPM [cases per month, i.e., referrals]." (Email from Joel Granier to Paul Dorsa et al., with attached email chain, Jan. 15, 2013, attached as **Exhibit 2**.)

52. Because this email was sent at a time before the EMR donation had been made, it is clear evidence of an agreement between Miraca and these physicians to provide at least 200 referrals per month in exchange for the EMR donation.

53. Mr. Roupp further discussed other referrals that were arranged by one of the potential beneficiaries, Dr. Joel Cohen, and then commented that if Miraca didn't "do the full donation which we have already committed to we will most likely lose all of their business let alone not gain their additional business and the business from their name." (*Id.* (emphasis added).)

54. Finally, a September 10, 2013 email regarding provider Coastal Gastroenterology & Hepatology provides another illustration of Miraca's knowledge of and use of illegal practices with respect to EMR donations. In this email from Miraca Regional Sales Director Scott Grybeck to Relator and others, Mr. Grybeck discusses the fact that a physician group "is opening

a new Surgery Center in three weeks and wants Provation MD [EMR software] installed. They know we probably can't get it installed by then but will begin sending 80-100 cpm global to start with more cases to ramp as soon as we install the system. . . . We have pushed as hard as we can to get the Path started sooner but they are standing firm on sending when we install." (*See* email from Scott Grybek to Paul Dorsa et al., with attached email chain, Sept. 10, 2013, attached as **Exhibit 3** (emphasis added)).

55. In the early days of Miraca's fraudulent EMR donation scheme, sales directors would "pitch" each EMR donation deal to Miraca executives on a case-by-case basis.

56. These pitches would include information regarding number of referrals that were promised in return for the EMR donation, the value of such referrals in terms of Medicare dollars and net profit, and how long it would take Miraca to recoup (via Medicare payments) the amount of the EMR donation (i.e., the ROI). (*See, e.g.,* "Old Safe Harbor Request Form" and accompanying email, attached as **Exhibit 4**.)

57. These EMR donation pitches were made to senior Miraca executives, including CEO Frank Basile, Vice President Gary Rainforth, Vice President Tom Zaves, Michael Feather, and others.

58. In addition, Miraca in-house counsel, Vice President Russell Farr and John Rasmussen, were aware of the parameters of the EMR donation program, the information collected and discussed, and the policies and practices of Miraca with respect to EMR donations.

59. Oftentimes, EMR donations were simply approved, as long as the number of referrals was sufficient to secure a large enough return on investment for Miraca.

60. Other times, Miraca would approve a lower EMR donation based on a low number of promised referrals. From time to time in these cases, Miraca sales directors would

bargain with the physician, sometimes returning to Miraca executives to request a higher donation. In these cases, higher donations would sometimes be approved.

61. As Miraca began increasing the number of its EMR donations, it instituted a bi-weekly conference call process during which individual sales directors each have 5 minutes to explain why a particular provider garnered an EMR donation (i.e., make a "pitch") and what level of EMR donation the sales director was requesting. During most calls, 5-10 EMR donations are considered. Initially, Relator used the conference calls in an effort to bring down the amounts Miraca was donating, rather than automatically making the 85% EMR donation to every physician. However, as the bi-weekly calls continued, Miraca sales directors began to use the lower EMR donation offers with physicians as bargaining chips, offering to increase the EMR donation in return for increased referrals.

62. During these conference calls, information is distributed, primarily by Miraca Business Analyst John Ripley, which includes the name of the physician or practice, the location of the physician or practice, the referral volume promised in return for the EMR donation, and the ROI for the physician or practice.

63. For some period of time, Miraca used an EMR donation request form which included the "anticipated CPM" (cases per month), the "CPTs per case" (CPT/billing codes per case), the "monthly CPTs," the "revenue per CPT," the cost per month for each case/CPT, and the margin per month for each case/CPT, as well as the anticipated total monthly cost and total monthly margin. (*See* "Donation" sheet, attached as **Exhibit 5**.)

64. In late 2012, Miraca switched to a new EMR donation request form. (*See, e.g.*, "2013 Safe Harbor Consideration Form," attached as **Exhibit 6**.) Notably, this form has had the "anticipated CPM," "monthly CPTs," revenue, variable cost, and margin information that was

present on the prior form stripped out. The new form appears to comply with the provisions of the Safe Harbors.

65. However, as the bi-weekly EMR donation conference calls continued, Miraca executives, including Relator, Senior VP Tom Zaves, and others, would receive copies of the new Safe Harbor Consideration Forms with hand-written notations on them indicating the forecasted "return on investment" (ROI) and sometimes the cases per month (CPM) expectation. (*See* "2013 Safe Harbor Consideration Forms" with hand-written ROI and CPM notations, attached as **Collective Exhibit 7**.) At times, sales directors would make comments on calls about promises for referrals that the director had secured from the physician or practice.

66. These ROI and CPM numbers were hand-written on the forms by Miraca Business Analyst John Ripley and were used to determine whether an EMR donation would be made to the provider, and at what level. Copies of the forms with the hand-written notations are destroyed.

67. The ROI and CPM numbers are calculated by Ripley, among others, and are based on the information that was present on the previous version of the EMR donation request form (i.e., promised number of referrals post-donation based on discussions with the physician, forecasted number of CPT codes per referral, cost to provide the services, reimbursement rates, and forecasted profit margin).

68. If approved, the EMR donation is signed off on by Miraca executives, including CEO Frank Basile, and Miraca makes the donation to the physician or practice.

69. Under the EMR donation program, Miraca has made donations totaling in excess of $6 million to over 180 providers in at least 32 states, and has received over 475,000 referrals from these providers.

D. The MU Consultation Fraud Scheme

70. Another program Miraca uses to generate referrals is its meaningful use consultation program. Essentially, Miraca gives free or deeply discounted training and services to physicians so that they can take advantage of Medicare's "meaningful use" bonuses.

71. Miraca's MU consultation program violates the Stark and Anti-Kickback laws because Miraca does not collect any payment from physicians for the valuable services it provides, Miraca offers the MU consultations as a method to generate referrals, Miraca rarely gets signed consultation agreements with the providers, and, even if Miraca were to collect the value it assigned to the MU consultations, this value ($500) is well below fair market value, solely based on the travel costs for and time spent by Miraca employees in delivering the MU consultations, nevermind the actual market value of such a service when compared to the possible money a physician might make as a result.

72. As demonstrated by internal Miraca emails, virtually no effort has been made by Miraca to bill providers for the MU consultations (even though such consultations can lead to these providers receiving thousands of dollars of bonuses), virtually no effort has been made by Miraca to collect payment for its MU consultations, and virtually no effort has been made by Miraca to get signed agreements with the providers with respect to the MU consultations, despite the fact that Relator raised concerns about the lack of executed contracts and payments. (*See* email from Meaghan Longyear to Paul Dorsa et al., with attached email chain, June 21, 2013, attached as **Exhibit 8**.)

73. When Dorsa began inquiring about the MU consultation program, Miraca had only one signed agreement. At the time of the filing of the Complaint, Miraca had done over 130

MU consultations, and while it now has 42 signed agreements, no invoices or bills have been sent, and no payments have been received from physicians.

74. Given the fact that Miraca uses these MU consultations as a way to generate referrals, these consultations create an impermissible financial relationship with these providers under the Stark Law, violated the Anti-Kickback statute, and the resulting claims constitute false claims under the False Claims Act.

75. Under the MU consultation program, Miraca has done MU consultations with at least 134 providers in over a dozen states, for a total of at least $67,000 (at the $500 value Miraca has estimated which, as discussed above, is below fair market value) of free services provided in violation of the Stark and Anti-Kickback laws.

VI. COUNTS

COUNT I
VIOLATIONS OF THE FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(A)
"Presentment False Claims"

76. Relator, on behalf of himself and the United States, re-alleges and incorporates paragraphs 1 through 76 above, as if set forth herein verbatim.

77. Defendant has knowingly presented or caused to be presented false or fraudulent claims to the United States for payment, in violation of the False Claims Act, 31 U.S.C. § 3829(a)(1)(A). Specifically, the Defendants knowingly submitted, or caused to be submitted, invoices and other requests and claims for payment to the United States Government containing claims for payment or approval of costs for procedures that were the knowing, intentional, willful, and/or reckless result of referrals garnered in violation of the Stark and Anti-Kickback laws, while certifying to the United States that Miraca was complying with all applicable Medicare rules, regulations, and statutes.

78. These claims were false, within the meaning of the False Claims Act, because the EMR donation and MU consultation arrangements were knowing, intentional, willful, and/or reckless violations of the Stark and Anti-Kickback laws, and the referrals that came about, and for which payment was received from Medicare, were a direct and intentional result of these violations. ("(f) HEALTH CARE FRAUD.— (1) KICKBACKS.—Section 1128B of the Social Security Act (42 U.S.C. 1320a–7b) is amended by adding at the end the following new subsection: '(g) In addition to the penalties provided for in this section or section 1128A, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code.'").

79. These false or fraudulent claims for payment or approval made by Defendant were material to the Government's decision to pay Defendant, and make Defendant liable under the False Claims Act.

80. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

COUNT II
VIOLATIONS OF THE FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(C)
"Conspiracy False Claims"

81. Relator, on behalf of himself and the United States, re-alleges and incorporates paragraphs 1 through 81 above, as if set forth herein verbatim.

82. Defendant conspired with its employees and EMR donation beneficiaries (physicians) to present the false claims to the United States as described above (i.e., make the "Presentment False Claims" in violation of 31 U.S.C. § 3729(a)(1)(A)). Defendant conspired with its employees and these doctors to get false claims paid by the United States; to wit: Defendant conspired to structure EMR donations in knowing, intentional, willful, and/or reckless

violation of the Stark and Anti-Kickback laws, and to submit Medicare claims based on referrals that were the fruit of these illegal EMR donation and MU consultation schemes. This conspiracy resulted in the presentation of thousands of false claims to the United States in violation of 31 U.S.C. § 3729(a)(1)(A).

83. These claims were false, within the meaning of the False Claims Act, because the EMR donation and MU consultation arrangements were knowing, intentional, willful, and/or reckless violations of the Stark and Anti-Kickback laws, and the referrals that came about, and for which payment was received from Medicare, were a direct and intentional result of these violations. ("(f) HEALTH CARE FRAUD.— (1) KICKBACKS.—Section 1128B of the Social Security Act (42 U.S.C. 1320a–7b) is amended by adding at the end the following new subsection: '(g) In addition to the penalties provided for in this section or section 1128A, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code.'").

84. By these actions, Defendant conspired to commit violations of 31 U.S.C. § 3729(a)(1)(A), in violation of 31 U.S.C. § 3729(a)(1)(C), making Defendant liable under the False Claims Act.

85. By virtue of this conspiracy, the United States suffered damages in an amount to be determined at trial.

COUNT III
PAYMENT BY MISTAKE OF FACT

86. Relator, on behalf of himself and the United States, re-alleges and incorporates paragraphs 1 through 86 above, as if set forth herein verbatim.

87. This is a claim for the recovery of monies paid by the United States to Defendant by mistake.

88. The claims made by Defendant to the United States were false, fraudulent, and otherwise unallowable, as described above, for failure to comply with applicable federal statutes and regulations that were conditions of payment, including but not limited to the Stark and Anti-Kickback laws and the False Claims Act.

89. The United States, acting in reasonable reliance on the accuracy and truthfulness of the information contained in these claims, as described above, paid to the Defendant certain sums of money to which it was not entitled, and Defendant is thus liable to account and pay such amounts, which are to be determined at trial, to the United States.

COUNT IV
UNJUST ENRICHMENT

90. Relator, on behalf of himself and the United States, re-alleges and incorporates paragraphs 1 through 90 above, as if set forth herein verbatim.

91. This is a claim for the recovery of monies by which Defendant has been unjustly enriched.

92. As described above, Defendant received, and/or has continued to maintain control over, monies of the United States to which it is not entitled.

93. By directly or indirectly obtaining monies of the United States to which it is not entitled, as described above, Defendant was unjustly enriched and is liable to account and pay such amounts, or the proceeds thereof, which are to be determined at trial, to the United States.

VI. PRAYERS FOR RELIEF

WHEREFORE, Relator, on behalf of himself and the United States, demands and prays that judgment be entered in her favor against Defendant, as follows:

1. On Counts I and II, under the False Claims Act, for triple the amount of the United States' damages plus interest and such civil penalties as are allowable by law,

together with the costs of this action and such other and further relief as may be just and proper;

2. On Count III, for payment by mistake of fact, for the damages sustained, plus prejudgment and post-judgment interest, costs, and all such further relief as may be just and proper;

3. On Count IV, for unjust enrichment, for the amount of unjust enrichment, plus pre-judgment and post-judgment interest, costs, and all such further relief as may be just and proper;

4. That judgment be entered in favor of the United States against the Defendant for actual damages, pre-judgment and post-judgment interest, litigation costs, investigative costs, disgorgement of all profits, and an accounting, to the fullest extent allowed by law, and for such further relief as may be just and proper.

Respectfully submitted,

NEAL & HARWELL, PLC

By: _____

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Counsel for Plaintiff Paul Dorsa

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been served, via hand-delivery and certified mail upon the following:

United States Attorney's Office
Middle District of Tennessee
110 Ninth Avenue South, Suite A-961
Nashville, TN 37203

and via certified, upon the following:

United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

this the 20th day of September, 2013.